

**TENNESSEE DEPARTMENT OF REVENUE  
REVENUE RULING #06-22**

**WARNING**

**Revenue rulings are not binding on the Department. This presentation of the ruling in a redacted form is information only. Rulings are made in response to particular facts presented and are not intended necessarily as statements of Departmental policy.**

**RE:** Coronary stents manufactured by Company A.

**SUBJECT**

Whether certain medical devices are exempt from sales and use tax as prosthetic devices.

**SCOPE**

Revenue rulings are statements regarding the substantive application of law and statements of procedure that affect the rights and duties of taxpayers and other members of the public. Revenue rulings are advisory in nature and are not binding on the Department.

**FACTS**

Coronary Artery Disease (“CAD”) occurs when the inner walls of the coronary arteries, which surround the heart, thicken due to plaque (a buildup of cholesterol, fatty deposits, calcium, and other elements). Angioplasty, one of the treatments for CAD, is a procedure used to open blocked arteries. A catheter (a thin tube) is inserted through the groin or wrist and then threaded through a major blood vessel to the site of the blockage. A small balloon on the tip of the catheter is then expanded to reduce the blockage. Many patients who have angioplasty also have coronary stent implantation. Stents are small tubular structures that are implanted into a vessel and expanded to fit the size, shape, and bend of the vessel wall. Stent implantation is performed to implant a stent that will remain in the blood vessel to hold open and support the blood vessel and improve blood flow. Stent implantation also reduces the risk of restenosis, a renarrowing of the artery following angioplasty.

Company A (hereinafter the “Taxpayer”) is a manufacturer and distributor of medical devices including different types of stent systems. The Taxpayer's products are primarily sold to physicians, hospitals, and other medical facilities. The majority of stent systems sold by the Taxpayer to hospitals in Tennessee are drug-eluting coronary stent systems. Drug-eluting stents are designed to perform the function of a coronary stent, and also

deliver a drug locally to minimize restenosis and reduce the need for additional treatment in the stented area. The stent system consists primarily of an expandable metal mesh tube, the stent, which helps restore blood flow by serving as a permanent vessel support for a newly widened artery formerly blocked by plaque deposits. The stent comes pre-mounted on a stent delivery system, which is used to deliver and deploy the stent, and then is thrown away. The stent delivery system is useless and valueless after the delivery and deployment of the stent.

The coating on the stent is composed of the drug Paclitaxel and a polymer. Paclitaxel is a cancer drug that is also used for the prevention of restenosis. The Paclitaxel/polymer coating has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls. When delivered locally to the wall of the coronary artery, it limits the growth of neointima (scar tissue) where stents have been implanted. The Taxpayer does not require a written prescription when it sells the coated stents. Warning labels are included on the Taxpayer's products indicating "Caution: Federal law restricts this product to sale by or on the order of a physician."

## **ISSUE**

Is a stent system exempt from sales and use tax as a prosthetic device?

## **RULING**

Yes.

## **ANALYSIS**

Under the Retailers' Sales Tax Act, Tenn. Code Ann. § 67-6-101 et. seq., the sale of tangible personal property is generally subject to sales and use tax unless an exemption applies. Several specific exemptions apply to the sale of medical equipment and supplies including the following exemption for orthotics and prosthetics:<sup>1</sup>

Tenn. Code Ann. § 67-6-314(5) provides as follows:

There is exempt from the sales tax imposed by the chapter. . .

(5) The sale or repair of prosthetics, orthotics, special molded orthopedic shoes, walkers, crutches, surgical supports of all kinds, and other similarly medical corrective or support appliances and devices.

A device is a prosthetic if it replaces a missing body part or augments the performance of a natural function. *Cordis Corp. v. Taylor*, 762 S.W.2d 138, 139 (Tenn. 1988). The

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<sup>1</sup> Legislation related to the Streamlined Sales and Use Tax Agreement, effective July 1, 2007, may result in changes regarding the application of sales and use tax sales of certain items of tangible personal property. The Department of Revenue encourages you to visit our website at [www.tennessee.gov/revenue](http://www.tennessee.gov/revenue) for updates.

court in *Cordis* held that an implantable cardiac pacemaker is a prosthetic because it replaces or augments the missing or reduced body function of providing a stimulus for the beating of a heart. *Id.* The court also held that a hydrocephalus valve system is a prosthetic because it is an artificial device that augments the natural flow of cerebral spinal fluid from the brain into the bloodstream. *Id.*

The stent manufactured by the Taxpayer is implanted into a coronary artery and augments the vessel's function which is to provide a conduit for the flow of blood to the heart. According to the Tennessee Supreme Court's interpretation of a prosthetic device in *Cordis*, devices which replace a body part or augment the performance of a natural function are considered exempt as prosthetic devices. Since the coronary stent augments the function of the coronary artery by keeping the artery open so that blood can flow through it, it qualifies as a prosthetic device under Tenn. Code Ann. § 67-6-314(5).<sup>2</sup>

The stent delivery system is considered disposable because it is useless and valueless after the preloaded stent is delivered. The Department has taken the position that a disposable unit that holds and delivers an exempt medical device constitutes a single item which qualifies for the exemption under Tenn. Code Ann. § 67-6-314(5). Based on this reasoning, the stent delivery system is also exempt as a prosthetic device.

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APPROVED: Loren L. Chumley  
Commissioner

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<sup>2</sup> It should be noted that the Taxpayer's stent also contains a drug which if sold separately may also be exempt from sales and use tax. Tenn. Code Ann. § 67-6-320(a) and (b) provides an exemption from sales and use tax for prescription drugs and medicines:

(a) There is exempt from the tax imposed by this chapter any prescription drug or medicine issued by a licensed pharmacist in accordance with an individual prescription written for the use of a human being by a practitioner of the healing arts licensed by the state of Tennessee.

(b) There is also exempt from the tax imposed by this chapter any prescribed drug or medicine sold to a practitioner of the healing arts licensed by the state of Tennessee or issued by a licensed pharmacist for use in the treatment of a human being.

To fall under this exemption, the item must be a drug or medicine and must be either (a) sold to a physician or (b) issued by a pharmacist to an individual in accordance with a physician's prescription. Accordingly, as long as the drug meets this test, it would be exempt from sales and use tax.